REMARKS

Claims 25-36 are pending in the above-identified application. Claims 13-24 have been cancelled. Support for new claims 25-36 is found in the original claims 1-12, as well as at pages 15-18 and 20-27 of the present specification.

Issues under 35 USC 112

Claims 13-24 have been rejected under 35 USC 112, second paragraphs as allegedly being indefinite because of certain terms previously recited in claims 13-24. These claims have been cancelled and the objected terms removed from the present claims such that this rejection should be withdrawn.

Issues under 35 USC 103(a)

Claims 13-24 have been rejected under 35 USC 103(a) as being unpatentable over Tanaka '043 (WO 99/24043 which corresponds to the translation in US No. 6,689,339 hereinafter "Tanaka '339") and as evidenced by Mosby's (Mosby's Medical, Nursing & Allied Heath Dictionary, 5th Edition, Kenneth N. Anderson Ed., New York, 1998, page 1528) and in view of Gibbins '258 (WO 01/49258).

The above rejection, as it pertains to new claims 25-36, is respectfully traversed based on the following reasons.

Present Invention and Its Advantages

The present invention is directed to a combination of materials for preparing an external preparation containing carbon dioxide wherein the materials are adapted for use on skin, as well as an external preparation with the reactants in contact with each other so as to generate carbon dioxide. As a means of explaining the background and advantages of the present invention, it is first noted that the mechanism of transdermal absorption (i.e. absorption through the skin) of carbon dioxide is considered to proceed as follows:

carbon dioxide (CO_2) reacts with water (H_2O) to generates carbonic acid (H_2CO_3) when it is dissolved in water according to equation (1): $CO_2 + H_2O \Rightarrow H_2CO_3$ (1)

In neutral or alkaline conditions, the formed carbonic acid is easily ionized and turned into hydrogen carbonate ions (HCO_3^-) and/ or carbonate ions (CO_3^{2-}) according to equations (2) and (3); but it is known that these ionic species are not percutaneously absorbed.

$H_2CO_3 \Rightarrow H^+ + HCO_3^-$ (2)

$HCO_3^- \Rightarrow H^+ + CO_3^{2-}$ (3).

In acidic conditions, however, carbon dioxide is easily dissolved while ionization of the generated carbonic acid is suppressed, and the rate of production for non-ionized carbonic acid, i.e. non-dissociated carbonic acid, is increased. The non-dissociated carbonic acid is a chemical substance which is formed by hydration of carbon dioxide. Carbon dioxide in such state is called "molecular-state" carbon dioxide. Carbon dioxide is percutaneously absorbed as non-dissociated carbonic acid. Under acidic conditions, a lot of non-dissociated carbonic acid is produced and percutaneous absorption of carbon dioxide is enhanced.

In the base agent of the present invention, equation (1) proceeds rightward, with the generation of molecular-state carbon dioxide, i.e. non-dissociated carbonic acid, being increased and the percutaneous absorption of carbon dioxide being advantageously enhanced. Moreover, the percutaneous absorption results in consumption of molecular carbon dioxide, i.e. non-dissociated carbonic acid, such that the reaction of equation (1) further proceeds rightward.

At the same time, the bubble formation of the generated carbon dioxide is hindered by the nonwoven cloth and which encourages dissolution of carbon dioxide into the water. As a result, the generation of non-dissociated carbonic acid and the percutaneous absorption of carbon dioxide is further enhanced. These are fundamental principles of the present invention.

Evidence of the effectiveness of the material of the present invention is shown, for example, in the evaluation tests described at pages 47-60 of the present specification.

Submission of Tanaka Declaration under 37 CFR 1.132

Further evidence of the unexpected, advantageous properties exhibited by the present invention is shown in the enclosed Declaration under 37 CFR 1.132 (the "Tanaka Declaration"). The Tanaka Declaration describes comparative tests between comparative examples based on Examples 112 and 125 of Tanaka '043/Tanaka '339 and examples of the present invention ("Practical Examples 6 and 13"). Examples 6 and 13 (present invention) both exhibit uexpected, advantageously improved bubble formation inhibition and vasodilation properties over Examples 112 and 125 based on Tanaka '043/Tanaka '339. Thus, the present invention exhibits advantageous properties over examples based on the primary cited reference.

Distinctions over Cited References

Tanaka '043/Tanaka '339 (hereinafter "Tanaka '339") discloses viscous compositions containing carbon dioxide wherein carbon dioxide bubbles are retained in an aqueous viscous composition. It is clear from a proper interpretation of Tanaka '339 that the described compositions provide for substantial generation of carbon dioxide in the form of bubbles. For example, as noted at column 14, lines 12-29, embodiments of the described compositions were evaluated with respect to the relative increase in carbon dioxide bubble generation which is described as the "foaming properties" of the evaluated compositions.

Tanaka '339 fails to disclose or suggest a combination of materials which include a base agent that suppresses carbon dioxide bubble generation for the purpose of advantageously enhancing percutaneous absorption thereof as in the present invention. The base agent employed in the present invention includes a nonwoven cloth impregnated with a viscous material containing an acid and water in order to provide an acidic environment so as to enhance percutaneous absorption of carbon dioxide in accordance with the principles of the present invention discussed above. Tanaka '339 describes carbon dioxide generation outside the gauze or sponge, whereas in contrast, such carbon dioxide generation occurs inside the nonwoven cloth of the present invention. Tanaka '339 includes evaluation tests of the described embodiments which assess the increase in carbon dioxide bubble formation or "foaming properties", whereas

in contrast, carbon dioxide is generated in substantially a non-bubble state in the present invention. Tanaka '339 describes a viscous composition which contains carbon dioxide bubbles, whereas in contrast, the viscous material employed in the base agent of the present invention contains an acid and water in addition to the carbon dioxide. Further, Tanaka '339 fails to disclose or suggest that an "elastic" polymeric structure be used, whereas in contrast, an elastic polymeric three-dimensional network structure is used in the base agent of the material of the present invention. Consequently, significant patentable distinctions exist between the present invention and Tanaka '339, such that the above-noted rejections based on this reference must be withdrawn.

It is submitted that the other cited references, i.e. Mosby's and Gibbins '258, fail to make up for the deficiencies noted with respect to Tanaka '339. Mosby's merely refers to a definition of the term "sponge", but fails to relate to carbon dioxide bubble generation compositions as described in Tanaka '339 and fails to suggest that such compositions should be combined with a viscous material, water and an acid in a nonwoven cloth as in the present invention.

Gibbins '258 discloses methods and compositions for delivery devices which employ a matrix of a polymer network and a non-gelable polysaccharide having oxygen and optionally active agents incorporated therein. Gibbins '258 discloses that gas, such as oxygen, may be trapped by a polymeric three-dimensional network structure and bubble formation thereby controlled. However, Gibbins '258 fails to address enhancement of percutaneous absorption of carbon dioxide by employing an appropriate acidic environment as in the present invention. Gibbins '258 is further removed from the present invention than Tanaka '339, such that all of the above-noted distinctions over Tanaka '339 also apply to Gibbins '258. Consequently, even if Gibbins '258 is hypothetically combined with Tanaka '339, the resulting hypothetical combined disclosure would still fail to described or suggest the features of the present and claimed invention. Therefore, the above-noted rejection based on the combination of these references must also be withdrawn.

Finally, all of Tanaka '339, Mosby's and Gibbins '258 fail to recognize the unexpected, advantageous properties exhibited by the present invention as described in the

present specification and as described in the enclosed Tanaka Declaration discussed above. Therefore, even if prima facie obviousness has been properly alleged, such obviousness has been rebutted by this evidence, such that the above rejections cannot be maintained.

It is submitted for the reasons above that the present claims define patentable subject matter such that this application should now be placed in condition for allowance.

If any questions arise in the above matters, please contact Applicant's representative, Andrew D. Meikle (Reg. No. 32,868), in the Washington Metropolitan Area at the phone number listed below.

If necessary, the Commissioner is hereby authorized in this, concurrent, and future replies to charge payment or credit any overpayment to Deposit Account No. 02-2448 for any additional fees required under 37.C.F.R. §§1.16 or 1.17; particularly, extension of time fees.

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Respectfully submitted,

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Enclosures: Tanaka Declaration under 37 CFR 1.132